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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,869	07/23/2003	Nicholas Lawrence Abbott	032026-0736	8011

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EXAMINER	
TRAN, MY CHAU T	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 08/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/625,869	ABBOTT ET AL.	
	Examiner	Art Unit	
	MY-CHAU T. TRAN	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *SEE OFFICE ACTION*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Application and Claims Status

1. Claims 1-20 are pending.

2. Claims 1-20 are treated on the merit in this Office Action.

Priority

3. This instant application is a continuation of 09/784,679 filed 02/15/2001, which claims benefit to a provisional application, 60/182,953 filed 02/16/2000. This instant application is granted the benefit of priority under 35 U.S.C 120 for 09/784,679 filed 02/15/2001, which is now US Patent 6,692,699, and under 35 U.S.C 119(e) for 60/182,953 filed 02/16/2000.

Information Disclosure Statement

4. The information disclosure statements (IDS) filed on 07/23/2003 have been reviewed, and its references have been considered as noted on PTO-1449 forms. *Note: Applicant indicated that copies of the documents were submitted in the application of 09/784,679.*

Specification

5. The disclosure is objected to because of the following informalities:

It is noted that this application appears to claim subject matter disclosed in prior Application No. 09/784,679 filed 02/15/2001. However, the specific reference to the earlier filed application must be made in the instant application, i.e. a reference to the prior application must

be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). This should appear as the first sentence(s) of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. ***Also, the current status of all nonprovisional parent applications referenced should be included.*** The instant specification does not include the status of the Application No. 09/784,679, which is now US Patent 6,692,699.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. Claims 8 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase '*a portion of*' in claims 8 and 16 is considered indefinite because it is unclear as to the means of measuring the degree of "*a portion of*". It is unclear what constitutes the metes and bounds of "*a portion of*", i.e. what degree is considered "*a portion of*" the listed claimed biomolecule recognition agents? Is its sequence length, functional group, or chemical structure? Thus, the claims 8 and 16 are considered indefinite and are rejected under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 2, 6, 14, 16, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Gupta et al. (*Science*, **1998**, 279(5359), pgs. 2077-2080).

> *The instant invention recites a rubbed substrate structure for use in a liquid crystal assay device (an apparatus). The apparatus comprises (a) a biochemical blocking compound chemically immobilized on a support thereby forming a biochemical blocking layer; and (b) a biomolecule recognition agent deposited on the same side of the support as the biochemical blocking layer, and the biomolecule recognition agent comprises a recognition site capable of selectively recognizing a target species.*
>
> *The surface of the biochemical blocking layer is a rubbed surface that possesses features that drive a uniform anchoring of liquid crystals when the liquid crystals contact the rubbed surface and resists non-specific adsorption of non- target species. These limitations of the biochemical blocking layer are interpreted as the functional limitations of the biochemical blocking layer.*
>
> *The kit claimed of claim 20 is interpreted as an apparatus with the structural limitations, i.e. a biochemical blocking compound chemically immobilized on a support and a biomolecule recognition agent, of the above claimed apparatus and a liquid crystal compound.*

Gupta et al. disclose a liquid crystal cell (see e.g. Abstract; pg. 2077, 1st col., lines 13-28; pg. 2077, 1st col., line 29 thru 3rd col., line 5; pg. 2077, fig. 1; pg. 2078, fig. 2). The liquid crystal cell comprises two supports, an anisotropic gold films (refers to instant claimed biochemical blocking layer), two self-assembled monolayers, a spacer that separate the two self-assembled monolayers (refers to instant claim 6), and a liquid crystal compound of 4-cyano-4'-

pentylbiphenyl (refers to instant claims 1, 2, and 20)(see e.g. pg. 2077, 3rd col., lines 6-35; pg. 2078, 1st col., lines 2-15; pg. 2078, figs. 2 and 3; pg. 2079, fig. 5). The anisotropic gold films comprise the properties that change the orientation of the liquid crystal and are greater than the nonspecific adsorption, but less than the specific adsorption (refers to the instant claimed functional limitation of the biochemical blocking layer)(see e.g. pg. 2079, 1st col., lines 6-12). The two self-assembled monolayers comprises a self-assembled monolayer form from the compound of biotin-$(CH_2)_2[(CH_2)_2O]_2NHCO(CH_2)_{11}SH$(BiSH) (the 'biotin' refers to instant claimed biomolecule recognition agent and instant claim 16) and a self-assembled monolayer form from the compound of $CH_3(CH_2)_7SH$(C_8SH) (see e.g. pg. 2077, 3rd col., lines 23-30). The support is a glass slide (refers to instant claim 14) (see e.g. pg. 2078, fig. 2). Thus, the liquid crystal cell of Gupta et al. anticipates the presently claimed invention.

9. Claims 1-3, 6, 10, 14, and 16 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gupta et al. (*Science*, **1998**, 279(5359), pgs. 2077-2080).

> *The instant invention recites a rubbed substrate structure for use in a liquid crystal assay device (an apparatus). The apparatus comprises (a) a biochemical blocking compound chemically immobilized on a support thereby forming a biochemical blocking layer; and (b) a biomolecule recognition agent deposited on the same side of the support as the biochemical blocking layer, and the biomolecule recognition agent comprises a recognition site capable of selectively recognizing a target species.*
>
> *The surface of the biochemical blocking layer is a rubbed surface that possesses features that drive a uniform anchoring of liquid crystals when the liquid crystals contact the rubbed surface and resists non-specific adsorption of non- target species. These limitations of the biochemical blocking layer are interpreted as the functional limitations of the biochemical blocking layer.*

Gupta et al. disclose a liquid crystal cell (see e.g. Abstract; pg. 2077, 1st col., lines 13-28; pg. 2077, 1st col., line 29 thru 3rd col., line 5; pg. 2077, fig. 1; pg. 2078, fig. 2). The liquid crystal cell comprises two supports, an anisotropic gold films (refers to instant claimed biochemical blocking layer), two self-assembled monolayers, a spacer that separate the two self-assembled monolayers (refers to instant claim 6), and a liquid crystal compound of 4-cyano-4'-pentylbiphenyl (refers to instant claims 1, 2, and 20)(see e.g. pg. 2077, 3rd col., lines 6-35; pg. 2078, 1st col., lines 2-15; pg. 2078, figs. 2 and 3; pg. 2079, fig. 5). The anisotropic gold films comprise the properties that change the orientation of the liquid crystal and are greater than the nonspecific adsorption, but less than the specific adsorption (refers to the instant claimed functional limitation of the biochemical blocking layer)(see e.g. pg. 2079, 1st col., lines 6-12). The two self-assembled monolayers comprises a self-assembled monolayer form from the compound of biotin-$(CH_2)_2[(CH_2)_2O]_2NHCO(CH_2)_{11}SH$(BiSH) (the 'biotin' refers to instant claimed biomolecule recognition agent and instant claim 16) and a self-assembled monolayer form from the compound of $CH_3(CH_2)_7SH$(C_8SH) (see e.g. pg. 2077, 3rd col., lines 23-30). The support is a glass slide (refers to instant claim 14) (see e.g. pg. 2078, fig. 2). Thus, the liquid crystal cell of Gupta et al. anticipates the presently claimed invention.

Alternatively, the claimed invention further differs from the prior art teachings only by the recitation of the process limitation of "*the biomolecule recognition agent is deposited on the same side of the support as the biochemical blocking layer before the biochemical blocking layer is rubbed*" of claim 3 and the process limitation of "*at least two regions of the rubbed surface are rubbed under different pressures, speeds, or for different lengths whereby the at least two regions of the rubbed surface have different sensitivities towards the target species*" of claim 10.

The claimed invention appears to be the same or obvious variations of the reference teachings, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to determine and/or compare the specific activities of the instant versus the reference Gupta et al. (*Science*, **1998**, 279(5359), pgs. 2077-2080). In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed device is different from the one taught by prior art and to establish the patentable differences. See *in re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ2d 1922(PTO Bd. Pat. App. & Int. 1989). Thus the device of Gupta et al. would still anticipate the presently claimed device since it meets all the structural limitation of the claimed device that is '*a biochemical blocking compound chemically immobilized on a support thereby forming a biochemical blocking layer; and (b) a biomolecule recognition agent deposited on the same side of the support as the biochemical blocking layer*'.

10. Claims 1, 2, 4, 14, 15, and 16 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Abbott et al. (US 6,277,489 B1).

The applied reference has a common inventor, Nicholas L. Abbott, with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The instant invention recites a rubbed substrate structure for use in a liquid crystal assay device (an apparatus). The apparatus comprises (a) a biochemical blocking

compound chemically immobilized on a support thereby forming a biochemical blocking layer; and (b) a biomolecule recognition agent deposited on the same side of the support as the biochemical blocking layer, and the biomolecule recognition agent comprises a recognition site capable of selectively recognizing a target species.

The surface of the biochemical blocking layer is a rubbed surface that possesses features that drive a uniform anchoring of liquid crystals when the liquid crystals contact the rubbed surface and resists non-specific adsorption of non- target species. These limitations of the biochemical blocking layer are interpreted as the functional limitations of the biochemical blocking layer.

Abbott et al. disclose multilayered device (see e.g. Abstract; col. 4, lines 28-35; col. 4, line 56 thru col. 5, line 1; col. 9, lines 14-41; col. 24, line 62 thru col. 25, line 15). The multilayered device (refers to instant claimed a rubbed substrate) comprises a substrate, a metal film layer, an organic layer, and a recognition moiety attached to the organic layer (see e.g. col. 4, lines 28-35; col. 9, lines 14-23). The substrate includes materials such as glass or silica (refers to instant claims 14 and 15) (see e.g. col. 9, line 56 thru col. 10, line 53). The recognition moiety (refers to instant claimed biomolecule recognition agent and claim 16) includes organic groups or biomolecules such as protein, nucleic acid, or peptide, and it is attached to the organic layer (refers to instant claim 2) (see e.g. col. 9, lines 22-35; col. 16, lines 38-49; col. 19, line 56 thru col. 20, line 27). The organic layer(s) (refers to instant claimed biochemical blocking layer) comprise monolayers, bilayers, and multilayers such as self-assembled monolayers (see e.g. col. 12, line 9 thru col. 16, line 34). The organic layer comprises a general structure of '$-SR^1(X^1)_n$' wherein R^1 (refers to instant claim 4) is a linking group between sulfur and X^1, and X^1 include compound such as recognition moiety, hydrophilic polymers, or the combination of both, i.e. X^1 comprises both a hydrophilic polymers and the recognition moiety (see e.g. col. 12, lines 44-52; col. 12, line 66 thru col. 13, line 16; col. 14, lines 40-55). The hydrophilic polymers include polymers such as polyethylene glycol (PEG), which is known in the art for its property of

reducing non-specific adsorption of biomolecules to the surface (see e.g. col. 14, lines 40-55; col. 15, lines 1-17). Thus, the multilayered particulate material of Abbott et al. anticipates the presently claimed invention.

Alternatively, the claimed invention further differs from the prior art teachings only by the recitation of t the functional limitation of the biochemical blocking layer that it '*possesses features that drive a uniform anchoring of liquid crystals when the liquid crystals contact the rubbed surface*'. The claimed invention appears to be the same or obvious variations of the reference teachings, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to determine and/or compare the specific activities of the instant versus the reference Gupta et al. (*Science*, **1998**, 279(5359), pgs. 2077-2080). In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed device is different from the one taught by prior art and to establish the patentable differences. See *in re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ2d 1922(PTO Bd. Pat. App. & Int. 1989). Thus, the multilayered particulate material of Abbott et al. would still anticipate the presently claimed device since it meets all the structural limitation of the claimed device that is '*a biochemical blocking compound chemically immobilized on a support thereby forming a biochemical blocking layer; and (b) a biomolecule recognition agent deposited on the same side of the support as the biochemical blocking layer*'.

11. Claims 1-3, 6, 7, 10, 14, 16, and 20 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Abbott et al. (US Patent 6,284,197 B1).

The applied reference has a common inventor, Nicholas L. Abbott, with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

> *The instant invention recites a rubbed substrate structure for use in a liquid crystal assay device (an apparatus). The apparatus comprises (a) a biochemical blocking compound chemically immobilized on a support thereby forming a biochemical blocking layer; and (b) a biomolecule recognition agent deposited on the same side of the support as the biochemical blocking layer, and the biomolecule recognition agent comprises a recognition site capable of selectively recognizing a target species.*
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> *The surface of the biochemical blocking layer is a rubbed surface that possesses features that drive a uniform anchoring of liquid crystals when the liquid crystals contact the rubbed surface and resists non-specific adsorption of non- target species. These limitations of the biochemical blocking layer are interpreted as the functional limitations of the biochemical blocking layer.*
>
> *The kit claimed of claim 20 is interpreted as an apparatus with the structural limitations, i.e. a biochemical blocking compound chemically immobilized on a support and a biomolecule recognition agent, of the above claimed apparatus and a liquid crystal compound.*

Abbott et al. disclose a device and methods for detecting analytes (see e.g. Abstract; col. 1, lines 22-27; col. 5, lines 13-59; col. 6, lines 54-65; col. 13, lines 4-31; col. 14, lines 6-32). In general, the device is multilayered and comprises one or more substrates, an organic layer, a recognition moiety, and a mesogenic layer (see e.g. col. 5, lines 13-59; col. 13, lines 4-31; col. 14, lines 6-32). The substrate includes materials such as glass (refers to instant claim 14) (see

e.g. col. 6, lines 54-65; col. 14, line 45 thru col. 15, line 10; fig 2). Additionally, the surface of the substrate is derivatized with reactive functional group wherein the organic layer is attached (see e.g. col. 21, lines 8-16; col. 21, lines 33-67). The organic layer (refers to instant claimed biochemical blocking layer) comprises monolayers, bilayers, and multilayers such as self-assembled monolayers (see e.g. col. 17, line 62 thru col. 18, line 4; col. 19, line 19 thru col. 20, line 3), and the organic layer surface activity, i.e. binding characteristics, is altered by attaching a monovalent moiety (refers to the instant claimed a biochemical compound)(see e.g. col. 25, lines 41-56). The recognition moiety (refers to instant claimed biomolecule recognition agent and claim 16) includes organic groups or biomolecules such as protein, nucleic acid, or peptide (see e.g. col. 26, lines 17-48). Moreover, the recognition moiety is attached to the organic layer through a spacer arm (refers to instant claims 2 and 7)(see e.g. col. 20, lines 4-52; col. 24, lines 60-66). The mesogenic layer is compound or mixture of compounds that is liquid crystals (see e.g. col. 10, lines 26-28; col. 30, lines 30-47). In one type of device, the device (refers to instant claim 20) comprises a first substrate with a first organic layer that comprises a recognition moiety, which interact with the analyte, a second substrate, and a mesogenic layer between the first and second substrate (see e.g. col. 5, lines 44-59; col. 20, lines 4-52; col. 40, line 36 thru col. 41, line 66). Thus, the device of Abbott et al. anticipates the presently claimed device.

Alternatively, the claimed invention further differs from the prior art teachings only by the recitation of the process limitation of "*the biomolecule recognition agent is deposited on the same side of the support as the biochemical blocking layer before the biochemical blocking layer is rubbed*" of claim 3 and the process limitation of "*at least two regions of the rubbed surface are rubbed under different pressures, speeds, or for different lengths whereby the at least two*

regions of the rubbed surface have different sensitivities towards the target species" of claim 10. The claimed invention appears to be the same or obvious variations of the reference teachings, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to determine and/or compare the specific activities of the instant versus the reference Abbott et al. (US Patent 6,284,197 B1). In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed device is different from the one taught by prior art and to establish the patentable differences. See *in re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ2d 1922(PTO Bd. Pat. App. & Int. 1989). Thus the device of Abbott et al. would still anticipate the presently claimed device since it meets all the structural limitation of the claimed device that is '*a biochemical blocking compound chemically immobilized on a support thereby forming a biochemical blocking layer; and (b) a biomolecule recognition agent deposited on the same side of the support as the biochemical blocking layer*'.

12. Claims 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Gupta et al. (*Science*, **1998**, 279(5359), pgs. 2077-2080).

The instant invention recites a kit for use in a liquid crystal assay (an apparatus). The apparatus comprises (a) at least one rubbed substrate structure; (b) a second surface that uniformly anchors liquid crystals; (c) a spacing material adapted to be placed between the rubbed substrate and the second surface that uniformly anchors liquid crystals; and (d) a liquid crystal compound.

Gupta et al. disclose a liquid crystal cell (see e.g. Abstract; pg. 2077, 1st col., lines 13-28; pg. 2077, 1st col., line 29 thru 3rd col., line 5; pg. 2077, fig. 1; pg. 2078, fig. 2). The liquid crystal cell comprises two supports, an anisotropic gold films (refers to instant claimed biochemical

blocking layer), two self-assembled monolayers, a spacer that separate the two self-assembled monolayers, and a liquid crystal compound of 4-cyano-4'-pentylbiphenyl (refers to instant claims 17-19)(see e.g. pg. 2077, 3rd col., lines 6-35; pg. 2078, 1st col., lines 2-15; pg. 2078, figs. 2 and 3; pg. 2079, fig. 5). The anisotropic gold films comprise the properties that change the orientation of the liquid crystal and are greater than the nonspecific adsorption, but less than the specific adsorption (refers to the instant claimed functional limitation of the biochemical blocking layer)(see e.g. pg. 2079, 1st col., lines 6-12). The two self-assembled monolayers comprises a mixed self-assembled monolayers wherein one self-assembled monolayer is form from the compound of biotin-$(CH_2)_2[(CH_2)_2O]_2NHCO(CH_2)_{11}SH$(BiSH) (the 'biotin' refers to instant claimed biomolecule recognition agent) and the second self-assembled monolayer form from the compound of $CH_3(CH_2)_7SH$(C_8SH) (refers to instant claimed second surface)(see e.g. pg. 2077, 3rd col., lines 23-30). The support is a glass slide (see e.g. pg. 2078, fig. 2). Thus, the liquid crystal cell of Gupta et al. anticipates the presently claimed invention.

13. Claims 17-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Abbott et al. (US Patent 6,284,197 B1)

The applied reference has a common inventor, Nicholas L. Abbott, with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The instant invention recites a kit for use in a liquid crystal assay (an apparatus). The apparatus comprises (a) at least one rubbed substrate structure; (b) a second surface that uniformly anchors liquid crystals; (c) a spacing material adapted to be placed between the rubbed substrate and the second surface that uniformly anchors liquid crystals; and (d) a liquid crystal compound.

Abbott et al. disclose a device and methods for detecting analytes (see e.g. Abstract; col. 1, lines 22-27; col. 5, lines 13-59; col. 6, lines 54-65; col. 13, lines 4-31; col. 14, lines 6-32). In general, the device is multilayered and comprises one or more substrates, an organic layer, a recognition moiety, and a mesogenic layer (see e.g. col. 5, lines 13-59; col. 13, lines 4-31; col. 14, lines 6-32). The substrate includes materials such as glass (refers to instant claim 14) (see e.g. col. 6, lines 54-65; col. 14, line 45 thru col. 15, line 10; fig 2). Additionally, the surface of the substrate is derivatized with reactive functional group wherein the organic layer is attached (see e.g. col. 21, lines 8-16; col. 21, lines 33-67). The organic layer (refers to instant claimed biochemical blocking layer) comprises monolayers, bilayers, and multilayers such as self-assembled monolayers (see e.g. col. 17, line 62 thru col. 18, line 4; col. 19, line 19 thru col. 20, line 3), and the organic layer surface activity, i.e. binding characteristics, is altered by attaching a monovalent moiety (refers to the instant claimed a biochemical compound)(see e.g. col. 25, lines 41-56). The recognition moiety (refers to instant claimed biomolecule recognition agent) includes organic groups or biomolecules such as protein, nucleic acid, or peptide (see e.g. col. 26, lines 17-48). Additionally, the recognition moiety is attached to the organic layer through a spacer arm (see e.g. col. 20, lines 4-52; col. 24, lines 60-66). The mesogenic layer is compound or mixture of compounds that is liquid crystals (see e.g. col. 10, lines 26-28; col. 30, lines 30-47). In one type of device, the optical cell (refers to instant claims 17 and 19) comprises two supports, an anisotropic gold films, two self-assembled monolayers, a spacer that separate the two self-

assembled monolayers, and a liquid crystal compound of 4-cyano-4'-pentylbiphenyl (refers to instant claim 18)(see e.g. col. 40, lines 36 thru col. 41, line 41; fig. 2). The anisotropic gold films comprise the properties that change the orientation of the liquid crystal and are greater than the nonspecific adsorption, but less than the specific adsorption (refers to the instant claimed functional limitation of the biochemical blocking layer)(see e.g. col. 42, lines 34-38). The two self-assembled monolayers comprises a self-assembled monolayer form from biotin-$(CH_2)_2[(CH_2)_2O]_2NHCO(CH_2)_{11}SH$(BiSH) (the 'biotin' refers to instant claimed biomolecule recognition agent) and a self-assembled monolayer form from $CH_3(CH_2)_7SH$(C_8SH) (refers to instant claimed second surface)(see e.g. col. 40, line 56 thru col. 41, line 19). The support is a glass slide (see e.g. fig. 2). Thus, the device of Abbott et al. anticipates the presently claimed device.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 1-7, 10, 14, and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abbott et al. (US Patent 6,284,197 B1; *filing date of 07/31/1998*) and Weetall (*Applied Biochemistry and Biotechnology*, **1993**, 41, pgs. 157-188).

The applied reference has a common inventor, Nicholas L. Abbott, with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Abbott et al. disclose a device and methods for detecting analytes (see e.g. Abstract; col. 1, lines 22-27; col. 5, lines 13-59; col. 6, lines 54-65; col. 13, lines 4-31; col. 14, lines 6-32). In general, the device is multilayered and comprises one or more substrates, an organic layer, a recognition moiety, and a mesogenic layer (see e.g. col. 5, lines 13-59; col. 13, lines 4-31; col. 14, lines 6-32). The substrate includes materials such as glass (refers to instant claim 14) (see e.g. col. 6, lines 54-65; col. 14, line 45 thru col. 15, line 10; fig 2). Additionally, the surface of the substrate is derivatized with reactive functional group wherein the organic layer is attached (see e.g. col. 21, lines 8-16; col. 21, lines 33-67). The organic layer (refers to instant claimed biochemical blocking layer) comprises monolayers, bilayers, and multilayers such as self-assembled monolayers (see e.g. col. 17, line 62 thru col. 18, line 4; col. 19, line 19 thru col. 20, line 3), and the organic layer surface activity, i.e. binding characteristics, is altered by attaching a

monovalent moiety (refers to the instant claimed a biochemical compound)(see e.g. col. 25, lines 41-56). The recognition moiety (refers to instant claimed biomolecule recognition agent and claim 16) includes organic groups or biomolecules such as protein, nucleic acid, or peptide (see e.g. col. 26, lines 17-48). Additionally, the recognition moiety is attached to the organic layer through a spacer arm (refers to instant claims 2 and 7)(see e.g. col. 20, lines 4-52; col. 24, lines 60-66). The mesogenic layer is compound or mixture of compounds that is liquid crystals (see e.g. col. 10, lines 26-28; col. 30, lines 30-47). In one type of device, the device (refers to instant claim 20) comprises a first substrate with a first organic layer that comprises a recognition moiety, which interact with the analyte, a second substrate, and a mesogenic layer between the first and second substrate (see e.g. col. 5, lines 44-59; col. 20, lines 4-52; col. 40, line 36 thru col. 41, line 66). In another type of device, the optical cell (refers to instant claims 17 and 19) comprises two supports, an anisotropic gold films, two self-assembled monolayers, a spacer that separate the two self-assembled monolayers, and a liquid crystal compound of 4-cyano-4'-pentylbiphenyl (refers to instant claim 18)(see e.g. col. 40, lines 36 thru col. 41, line 41; fig. 2). The anisotropic gold films comprise the properties that change the orientation of the liquid crystal and are greater than the nonspecific adsorption, but less than the specific adsorption (refers to the instant claimed functional limitation of the biochemical blocking layer)(see e.g. col. 42, lines 34-38). The two self-assembled monolayers comprises a self-assembled monolayer form from biotin-$(CH_2)_2[(CH_2)_2O]_2NHCO(CH_2)_{11}SH$(BiSH) (the 'biotin' refers to instant claimed biomolecule recognition agent) and a self-assembled monolayer form from $CH_3(CH_2)_7SH$(C_8SH) (refers to instant claimed second surface)(see e.g. col. 40, line 56 thru col. 41, line 19). The support is a glass slide (see e.g. fig. 2).

Additionally, the claimed invention further differs from the prior art teachings only by the recitation of the process limitation of "*the biomolecule recognition agent is deposited on the same side of the support as the biochemical blocking layer before the biochemical blocking layer is rubbed*" of claim 3 and the process limitation of "*at least two regions of the rubbed surface are rubbed under different pressures, speeds, or for different lengths whereby the at least two regions of the rubbed surface have different sensitivities towards the target species*" of claim 10. The claimed invention appears to be the same or obvious variations of the reference teachings, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to determine and/or compare the specific activities of the instant versus the reference Abbott et al. (US Patent 6,284,197 B1). In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed device is different from the one taught by prior art and to establish the patentable differences. See *in re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ2d 1922(PTO Bd. Pat. App. & Int. 1989).

The device of Abbott et al. does not expressly include a crosslinking agent that immobilizes the biochemical blocking compound onto the support, and the crosslinking agent is glutaraldehyde.

Weetall teaches a method of immobilizing protein on an inorganic support by way of a bifunctional "linker" substance (see e.g. pg. 166, lines 13-19). One type of bifunctional linker is glutaraldehyde (see e.g. pg. 167, lines 1-12; pg. 167, fig. 6).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a crosslinking agent that immobilizes the biochemical blocking

compound onto the support, and the crosslinking agent is glutaraldehyde as taught by Weetall in the device of Abbott et al. One of ordinary skill in the art would have been motivated to include a crosslinking agent that immobilizes the biochemical blocking compound onto the support, and the crosslinking agent is glutaraldehyde in the device of Abbott et al. would be a choice of experimental design and is considered within the purview of the cited prior art. Additionally, both Abbott et al. and Weetall disclose that there is a variety of reaction type that is available for the functionalization of the substrate surface and thus the type use depend on the specific needs of the application (Abbott: col. 21, lines 17-26; Weetall: pg. 182, lines 27-32). Furthermore, one of ordinary skill in the art would have had a reasonable expectation of success in the combination of Abbott et al. and Weetall since Weetall shown the success of derivatizing the inorganic substrate with the glutaraldehyde (pg. 167, fig. 6).

17. Claims 1-3, 6-14, and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abbott et al. (US Patent 6,284,197 B1; *filing date of 07/31/1998*) and Anawis et al. (US Patent 5,091,318).

The applied reference has a common inventor, Nicholas L. Abbott, with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Abbott et al. disclose a device and methods for detecting analytes (see e.g. Abstract; col. 1, lines 22-27; col. 5, lines 13-59; col. 6, lines 54-65; col. 13, lines 4-31; col. 14, lines 6-32). In general, the device is multilayered and comprises one or more substrates, an organic layer, a recognition moiety, and a mesogenic layer (see e.g. col. 5, lines 13-59; col. 13, lines 4-31; col. 14, lines 6-32). The substrate includes materials such as glass (refers to instant claim 14) (see e.g. col. 6, lines 54-65; col. 14, line 45 thru col. 15, line 10; fig 2). Additionally, the surface of the substrate is derivatized with reactive functional group wherein the organic layer is attached (see e.g. col. 21, lines 8-16; col. 21, lines 33-67). The organic layer (refers to instant claimed biochemical blocking layer) comprises monolayers, bilayers, and multilayers such as self-assembled monolayers (see e.g. col. 17, line 62 thru col. 18, line 4; col. 19, line 19 thru col. 20, line 3), and the organic layer surface activity, i.e. binding characteristics, is altered by attaching a monovalent moiety (refers to the instant claimed a biochemical compound)(see e.g. col. 25, lines 41-56). The recognition moiety (refers to instant claimed biomolecule recognition agent and claim 16) includes organic groups or biomolecules such as protein, nucleic acid, or peptide (see e.g. col. 26, lines 17-48). Additionally, the recognition moiety is attached to the organic layer through a spacer arm (refers to instant claims 2 and 7)(see e.g. col. 20, lines 4-52; col. 24, lines 60-66). The mesogenic layer is compound or mixture of compounds that is liquid crystals (see e.g. col. 10, lines 26-28; col. 30, lines 30-47). In one type of device, the device (refers to instant claim 20) comprises a first substrate with a first organic layer that comprises a recognition moiety, which interact with the analyte, a second substrate, and a mesogenic layer between the first and second substrate (see e.g. col. 5, lines 44-59; col. 20, lines 4-52; col. 40, line 36 thru col. 41, line 66). In another type of device, the optical cell (refers to instant claims 17 and 19)

comprises two supports, an anisotropic gold films, two self-assembled monolayers, a spacer that separate the two self-assembled monolayers, and a liquid crystal compound of 4-cyano-4'-pentylbiphenyl (refers to instant claim 18)(see e.g. col. 40, lines 36 thru col. 41, line 41; fig. 2). The anisotropic gold films comprise the properties that change the orientation of the liquid crystal and are greater than the nonspecific adsorption, but less than the specific adsorption (refers to the instant claimed functional limitation of the biochemical blocking layer)(see e.g. col. 42, lines 34-38). The two self-assembled monolayers comprises a self-assembled monolayer form from biotin-$(CH_2)_2[(CH_2)_2O]_2NHCO(CH_2)_{11}SH$(BiSH) (the 'biotin' refers to instant claimed biomolecule recognition agent) and a self-assembled monolayer form from $CH_3(CH_2)_7SH$(C_8SH) (refers to instant claimed second surface)(see e.g. col. 40, line 56 thru col. 41, line 19). The support is a glass slide (see e.g. fig. 2).

Additionally, the claimed invention further differs from the prior art teachings only by the recitation of the process limitation of "*the biomolecule recognition agent is deposited on the same side of the support as the biochemical blocking layer before the biochemical blocking layer is rubbed*" of claim 3 and the process limitation of "*at least two regions of the rubbed surface are rubbed under different pressures, speeds, or for different lengths whereby the at least two regions of the rubbed surface have different sensitivities towards the target species*" of claim 10. The claimed invention appears to be the same or obvious variations of the reference teachings, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to determine and/or compare the specific activities of the instant versus the reference Abbott et al. (US Patent 6,284,197 B1). In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed

device is different from the one taught by prior art and to establish the patentable differences. See *in re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ2d 1922(PTO Bd. Pat. App. & Int. 1989).

The device of Abbott et al. differs from the presently claimed invention by failing to include using the blocking agent of bovine or equine serum albumin.

Anawis et al. disclose a device for detecting the presence of an analyte (antibody) in a test sample. The assay device includes a solid phase and the ligand (antigen) is immobilized upon the solid phase (see e.g. col. 2, lines 52-55). In order to prevent non-specific binding of protein to the solid phase when the reaction mixture containing a specific binding member is contacted to the solid phase by using a blocking agent such as bovine or equine serum albumin.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include using the blocking agent of bovine or equine serum albumin as taught by Anawis et al. for the biochemical blocking compound in the device of Abbott et al. One of ordinary skill in the art would have been motivated to include using the blocking agent of bovine or equine serum albumin as taught by Anawis et al. for the biochemical blocking compound in the device of Abbott et al. for the advantage of prevent non-specific binding of the analyte such as protein since both Abbott et al. and Anawis et al. disclose an assay device for detecting binding of an analyte on the surface of a solid phase (Abbott: col. 40, lines 36-38; Anawis: col. 7, lines 15-19). Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the combination of Abbott et al. and Anawis et al. because both disclose Abbott et al. and Anawis et al. immobilizing bovine serum albumin on the surface of the support (Abbott: col. 42, lines 2-20; Anawis: col. 2, lines 52-55).

Double Patenting

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 1, 14, and 16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 21, and 23 of U.S. Patent No. 6,277,489 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed device of U.S. Patent No. 6,277,489 B1 has overlapping scope since the device of the instant application is generic to the device of the presently claimed device of U.S. Patent No. 6,277,489 B1, or in other words, claims 1, 14, and 16 are anticipated by claims 1-3, 21, and 23 of U.S. Patent No. 6,277,489 B1. Specifically, the structural features of both devices are a multilayered support comprising a biochemical layer (refers to the organic layer of U.S. Patent No. 6,277,489 B1 and the instant claimed biochemical blocking layer) and a recognition moiety. Thus, the examined claims would have been obvious over the claims of U.S. Patent No. 6,280,595 B1.

20. Claims 1, 16, 17, and 20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, and 11 of U.S. Patent No.

6,858,423 B1). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed device of U.S. Patent No. 6,858,423 B1 has overlapping scope since the device of the instant application is generic to the device of the presently claimed device of U.S. Patent No. 6,858,423 B1, or in other words, claims 1, 16, 17, and 20 are anticipated by claims 1-5, and 11 of U.S. Patent No. 6,858,423 B1. Specifically, the structural features of both devices are a multilayered support comprising a biochemical layer (refers to the organic layer of U.S. Patent No. 6,858,423 B1 and the instant claimed biochemical blocking layer); a recognition moiety; a second substrate; an interior portion (refers to instant claimed spacer of claim 17); and a mesogenic layer (refers to instant claimed liquid crystal compound). Thus, the examined claims would have been obvious over the claims of U.S. Patent No. 6,858,423 B1.

21. Claims 1, 8, 9, 11, 12, 16, and 20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 8-10, and 14 of copending Application No. 10/934,023. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed device of has overlapping scope since the device of copending Application No. 10/934,023 the instant application is generic to the device of the presently claimed device of copending Application No. 10/934,023, or in other words, claims 1, 8, 9, 11, 12, 16, and 20 are anticipated by claims 1, 8-10, and 14 of copending Application No. 10/934,023. Specifically, the structural features of both devices are a multilayered support comprising a biochemical blocking layer, a binding agent, and a liquid

crystal compound. Thus, the examined claims would have been obvious over the claims of copending Application No. 10/934,023.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 571-272-0810. The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
August 19, 2005

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